REMARKS

Claims 1 and 3-6 are pending in the application. Claims 6-51 have been canceled pursuant to their having been withdrawn owning to a restriction requirement. The cancellation of claims 6-51 is without prejudice to applicant's right to submit those claims in a subsequent divisional application.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,536,267 to Edwards et al. ("Edwards").

Claims 1-5 stand also rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,304,120 to Crandell et al. ("Crandell").

In order to more specifically identify applicant's invention and facilitate the Examiner's understanding of the differences between applicant's invention and the prior art particularly as exemplified by Edwards and Crandell, applicant has amended claim 1 to incorporate the limitations of claim 2 (which is canceled herein) and further language describing a flow through structure of applicant's medical instrument.

As set forth in amended claim 1, an endoscopic medical instrument comprises an elongate tubular member and a plurality of hollow needle elements connected to one end of the elongate member so that each of the hollow needle elements communicates with a lumen of the elongate tubular member. The elongate tubular member is sufficiently flexible, long and narrow to traverse a biopsy channel of a flexible fiberoptic endoscope. The needle elements extend in a direction away from the one end of the elongate tubular member and are each convex on an outer side facing away from the other needle element and concave on an inner side facing the other needle elements so that the needle elements

together define a bulbous ovoid shape, with tips of the needle elements angled inwardly at a distal tip of the medical instrument. The needle elements each are sufficiently flexible to negotiate bends in the biopsy channel. Each of the hollow needle elements is provided with at least one aperture so that fluid may be delivered through the elongate tubular member and the hollow needle elements and out through the apertures in the hollow needle elements.

The Edwards reference discloses a multiple electrode ablation apparatus having a plurality of hollow electrodes 20 each extending longitudinally through a guide catheter 12 (Figures 6 and 7). The electrodes are not connected to a distal end of the guide catheter so that each of the electrodes (20) communicates at a proximal end with a lumen of the catheter (12) and so that fluid may be delivered through the catheter into the electrodes. In the device of Edwards, the electrodes (20) pass longitudinally along the catheter and out through a closed distal end of the catheter. Proximal ends of the electrodes are presumably located outside the catheter at the proximal end thereof. Liquid flows through each of the electrodes separately and does not flow from the catheter into the electrodes. The electrodes do no communicate at their proximal ends with the lumen of the catheter.

The Crandell reference discloses an apparatus for delivering a drug or gene therapy composition to endothelial cells of a blood vessel wall. The apparatus includes a plurality of delivery tubes (16) that pass through a tubular guide member (24). Each delivery tube extends longitudinally through the guide member. The delivery tubes are not connected at their proximal ends to the guide tube. The delivery tubes do not communicate with a lumen of the guide tube. The delivery tubes are not needles. They

do not have pointed ends. For all these reasons, amended claim 1 distinguishes over the teachings of Crandell.

Applicant's invention is particularly designed for use in an endoscopic procedure to raise polyps from a colon wall so that the polyps may be removed without perforating the colon. This device is invaluable in the fight against colon cancer. Colonic polyps, if left in the patient, result in colon cancer, and therefore must be removed. A colonic perforation which may occur during polypectomy necessitates open abdominal surgery that involves a colon resection, pain for the patient, and a prolonged hospital stay and convalescence. An instrument that makes polypectomy safer is of utmost importance. Applicant requests that the examiner to consider the invention carefully in view of the benefit that patients will receive by adding this novel instrument to the armamentarium of gastroenterology devices.

Applicant notes in this regard that the claimed device has been made and used in patients. It works extremely well. The hollow needle elements are directly connected to the distal end of a catheter. Therefore, the fluid is injected into the proximal end of the catheter and comes out of the needles and into tissue.

The present invention functions in order to render polypectomy safer. It is important to understand that the colonic wall is only 1/2 a cm thick. If a flat polyp is burnt off, a colonic perforation is likely to occur, unless the polyp is raised beforehand to form an artificial stalk. (That is why applicant calls her device "THE PEDUNCULATOR".) Once the endoscopist has successfully raised the flat (or sessile) polyp by means of a saline injection underneath the polyp, a safety buffer has been created. Now, instead of burning an area that is only 1/2 cm thick, the endoscopist burns

through an area that is 1.5 cm thick. Thus, the procedure is made three times as safe for the patient.

The specification has been amended to provide antecedent support for claim language introduced herein. The added phrase is not new matter but rather describes a clear feature of applicant's device.

A Request for Continued Examination and an Extension Request accompany this Amendment.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

Conclusion

For the foregoing reasons, independent claim 1, as well as claims 3-5 dependent therefrom, is deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

By: _____

R. Neil Sudol
Reg. No. 31,669

714 Colorado Avenue
Bridgeport, CT 06605-1601
(203) 366-3560

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